

Remarks/Arguments

Claims 1, 6-9, 11, 15-17, 21-32, and 34 remain in this application.

Claim Rejections- 35 U.S.C. §103(a)

1, 6-9, 11, 15-17, 21-32, and 34 remain rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,106,864 to Dolan et al. (hereinafter "Dolan") and U.S. Patent No. 5,800,422 to Dong et al. (hereinafter "Dong") and U.S. Patent No. 6,099,859 to Cheng (hereinafter "Cheng").

The Office Action asserts that Dolan teaches oral dosage forms of actives and teaches that a matrix comprising the active can be coated with an impermeable coating (see column 2, lines 34-52 and 53-57). It is submitted, however, that Dolan actually teaches that the impermeable coating is non-enteric (as noted in the description at Column 3, lines 15-18 with respect to the examples provided) and must have an aperture (see column 3, lines 1-7 and lines 11-21).

The Office Action also asserts that Dolan teaches that ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers (see column 3, lines 7-38). (Please note that ethyl cellulose is not a cellulose ester; as acknowledged by the Office Action). Dolan's coat is either impermeable with an aperture, as noted in (c) at column 2, lines 42-44 and column 3, lines 11-21, or the coat can have low aqueous solubility (e.g. water soluble at pH >5), as noted in (d) at column 2, lines 46-47, and column 3, lines 22-30. Dolan teaches the use of non-enteric cellulose esters (soluble in the acidic pH range), such as cellulose acetate, in conjunction with an impermeable coat, as noted in (c) at column 3, lines 11-21, and with a semi-permeable coat, as noted in (e) at column 3, lines 32-37. Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0, as claimed in the present invention. Non-enteric coatings are not soluble in a pH of above about 5.0. PEG is used in the coat of the claimed invention to achieve the non-permeability (e.g. not permeable; no drug goes through) of the coat that is soluble at a pH of above about 5.0. Moreover, if the coating of Dolan is non-permeable, it would

include an aperture and be non-enteric, as taught at Column 3, lines 15-18. Dolan does not teach or suggest a coat being both non-permeable and soluble in a pH of above about 5.0.

The Office Action asserts that Dong teaches the use of PEG in a coating and that it would have been obvious to include PEG in the coating of Dolan. Applicant respectfully disagrees. The specific combination of the claimed invention (e.g. polymer and PEG) yields a coating that is both non-permeable and soluble in a pH of above about 5.0. One skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat (e.g. non-permeable coat) since an impermeable coat of Dolan is associated with non-enteric coats (dissolve at pH below 5.0; see Column 3, lines 15-18 of Dolan).

The Office Action also asserts that Cheng teaches that PEG is a flux-enhancing agent, which allows the drug to be released through the pores of the coat. The Office Action further asserts that it would have been obvious to modify the invention of Dolan to include the PEG to enhance the release of the drug through the pores. As noted above, the PEG is used in the claimed invention to aid in making the coating non-permeable. Therefore, one skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat since Cheng clearly teaches that PEG makes the coating permeable.

Office Action's Response to Applicants Arguments

The Office Action asserts that Dolan teaches that the active ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) which are impermeable and soluble at a pH greater than 5 (Column 3, lines 7-38). Moreover, the Office Action asserts that where shellac or phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) serve as the coating materials the limitation of the invention with respect to the coating is met. The Office Action notes that the instant specification employs said polymers as coating materials (specification paragraph 39). Applicant disagrees. Dolan does not meet the limitations of the coating. As outlined above, the claimed invention is directed to the specific combination of the claimed invention (e.g. polymer and PEG) yields a coating that is both non-permeable and soluble in a pH of above about 5.0.

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The Office Action asserts that Applicants argue that Dolan teaches that impermeable coating is non-enteric and must have an aperture. The Office Action asserts that Dolan teaches that the tablet is coated with cellulose acetate and polyvinyl acetate phthalate which would meet the limitation of coating types recited in instant claims 9 and 21 and which would meet the pH solubility limitations recited in the claims (Dolan column 3 lines 7-38). Applicant submits, again, that cellulose acetate is non-enteric and would not meet the pH solubility limitations recited in the claims (refer to previous Response and Declaration dated December 4, 2008).

The Office Action notes that the instant application, like Dolan, teaches that cellulose acetate and polyvinyl acetate phthalate are desired coatings (instant claims 9 and 21). Applicant reiterates that cellulose acetate is non-enteric and does not fall within the limitations of claims 9 and 21. The instant claims employ comprising language which renders polymer coatings open to having an aperture. Dolan's coat is either impermeable with non-enteric materials and an aperture, as noted in (c) at column 3, lines 11-21, or the coat can have low aqueous solubility (e.g. water soluble at pH >5), as noted in (d) at column 2, lines 46-47, and column 3, lines 22-30. Dolan teaches the use of non-enteric cellulose esters (soluble in the acidic pH range (below pH of 5)), in conjunction with an impermeable coat, as noted in (c) at column 3, lines 11-21, and with a semi-permeable coat, as noted in (e) at column 3, lines 32-37. Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0, as claimed in the present invention.

The Office Action notes that Applicants argue that Dolan does not teach or suggest an encasement coat being both non-permeable and soluble in a pH of above about 5.0 as instantly claimed. Applicant provides a declaration showing that cellulose acetate does not meet the requirement of being both non-permeable and soluble in a pH of above about 5.0 as claimed. The Office Action asserts that Applicants have shown this statement to be true with respect to cellulose acetate, the Examiner argues that Dolan teaches some of the same coating materials (e.g. polyvinyl acetate phthalate) as those recited in instant claims 9 and 21 for the tablet; therefore it is expected that Dolan's coatings (e.g. polyvinyl acetate phthalate) are both non-permeable and soluble at a pH of above about 5.0. To clarify, Applicant's Declaration shows

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that cellulose acetate does not satisfy the requirement of being soluble in a pH of above about 5.0. The Declaration is directed to solubility not impermeability. The instant invention is directed to the specific combination of a polymer and PEG to achieve both properties of the coating: impermeability and solubility at a pH of above about 5.0.

The Office Action notes that Applicants argue that the specific combination of the claimed invention, i.e. the combination of polymer and PEG, yields a coating that is both non-permeable and soluble at a pH of above about 5.0. An artisan in the field would not have considered adding PEG to the coating of Dolan to achieve an impermeable coat since an impermeable coat of Dolan is associated with non-enteric coatings. The Office Action maintains that it would have been obvious to include the PEG taught by Dong or Chen to control the release of the drug through the polymeric coating. PEG is a common material used in coats for tablets for drug control release. Applicant disagrees. One skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat (e.g. non-permeable coat) since an impermeable coat of Dolan is associated with non-enteric coats (dissolve at pH below 5.0; see Column 3, lines 15-18 of Dolan). There would be no point to add PEG since impermeability was already achieved with the non-enteric coating of Dolan. Impermeability in Dolan is associated with non-enteric coats only.

For these reasons, it is respectfully submitted that Claims 1, 6-9, 11, 15-17, 21 to 32, and 34 are patentable over Dolan, Dong and Cheng. Dong and Cheng do not overcome the above-noted deficiencies of Dolan.

Conclusion

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of all of the pending claims 1, 6-9, 11, 15-17, 21-32, and 34, and the issuance of a Notice of Allowability are respectfully solicited.

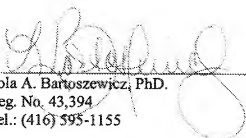
In the event the Examiner considers personal contact advantageous to the disposition of this case, he/she is hereby authorized to call Kimberly A. McManus, at Telephone Number (416) 849-8405.

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In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. **192253**, referencing docket number **9577-25 LAB**.

Respectfully submitted,
SIM & McBURNEY

By



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